

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MERCK SHARP & DOHME
PHARMACEUTICALS, SRL,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., and TEVA PHARMACEUTICAL
INDUSTRIES, LTD.

Defendants.

C.A. No. 07-1596 (GEB) (JJH)

**JOINT STATEMENT OF LAW
REGARDING OBVIOUSNESS**

1. A determination of obviousness under 35 U.S.C. § 103 of the Patent

Statute is a question of law based upon the underlying facts, for which:

“the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.”

Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966).

2. The Supreme Court recently reconfirmed that the *Graham* factors

“continue to define the inquiry that controls” the obviousness analysis. *KSR Int’l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007).

3. Section 103 of the Patent Statute provides that obviousness must be

determined from the perspective of “a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a).

4. The Supreme Court explained that “[t]o determine whether there was an

apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to ... the background knowledge possessed by a person having ordinary skill in the art.” *KSR*, 127 S. Ct. at 1740-41.

5. A person of ordinary skill is a hypothetical person “presumed to be aware

of all the pertinent prior art.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *Custom Accessories, Inc. v. Jeffrey-Allan Indust., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

6. Failure to show *prima facie* obviousness means the claims are not deemed

invalid for obviousness, ending the inquiry. *See Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1345 (Fed. Cir. 2000).

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**MSD'S ADDITIONAL STATEMENT OF LAW
REGARDING OBVIOUSNESS**

I. THE LAW OF OBVIOUSNESS

A. The Standard To Invalidate Patent Claims Is High: Clear and Convincing Evidence

1. Under the Patent Statute, Claims 18 – 22 of the '473 patent are presumed valid. *See* 35 U.S.C. § 282.

2. The statutory presumption of validity places the high burden of proving that Claims 18 – 22 of the '473 patent are invalid by the standard of clear and convincing evidence. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001).

3. The clear and convincing standard require evidence that would give the fact finder “an abiding conviction that the truth of [the] factual contentions [is] highly probable.” *Intel Corp. v. U.S. Int’l Trade Comm’n*, 946 F.2d 821, 830 (Fed. Cir. 1991) (citations omitted).

B. Obviousness Standards

1. A determination of whether claims 18 – 22 of the '473 patent are invalid for obviousness under 35 U.S.C. § 103 is a question of law based on the facts concerning: (i) the scope and content of the prior art; (ii) the level of ordinary skill in the art; (iii) the differences between the prior art and the claims at issue; and (iv) secondary considerations of nonobviousness, such as commercial success, unexpected results, failure of others, long-felt need, and copying. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court recently reaffirmed that the *Graham* factors “continue to define the inquiry that controls” an obviousness analysis. *KSR Int’l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007).

2. Obviousness determinations proceed in two stages. In the first stage, it must be established by clear and convincing evidence that the claimed invention is *prima*

facie obvious under the first three *Graham* factors. See *Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 974-75 (Fed. Cir. 1986). In cases concerning a new chemical compound like montelukast, a party must “identify some reason that would have led a chemist to modify a known compound in a particular manner to establish a *prima facie* case of obviousness of a new claimed compound.” *Takeda Chem. Indus. Ltd. v. Alphapharm Pty. Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007), *cert denied*, 128 S. Ct. 1739 (2008) (affirming a holding of nonobviousness).

3. The obviousness inquiry ends if the patent challenger fails to show *prima facie* obviousness. See *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1345 (Fed. Cir. 2000).

4. The patent law recognizes the *prima facie* standard in two contexts: (1) a patent infringer’s initial burden of proving obviousness under 35 U.S.C. § 103, in which the statutory presumption of patent validity applies, and (2) Patent and Trademark Office (“PTO”) obviousness rejections in the context of examining patent applications, under which the statutory presumption of patent validity does not apply. See *Rohm and Haas Co. v. Mobil Oil Corp.*, 895 F.2d 1421, n.** (Fed. Cir. 1990).

5. The *prima facie* context that applies in this case is the first, *i.e.*, the *prima facie* obviousness standard under 35 U.S.C. § 103. See *id.* Accordingly, cases addressing the *prima facie* standard for obviousness in the context of patent applications before the PTO (*e.g.*, *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995)) apply the standard differently than is applicable in this case. See *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359-60 (Fed. Cir. 2007).

6. In the second stage of the obviousness analysis, a patentee may come forward with evidence to demonstrate that the invention is not obvious (*i.e.*, the fourth *Graham* factor). *Prima facie* evidence may be rebutted not only by showing that the invention has an unexpected superior property compared to the prior art, but also by secondary considerations such as commercial success, failure of others to solve the problem, copying, and the invention's satisfaction of a long-felt but unsolved need. *Graham*, 383 U.S. at 17.

7. These objective secondary considerations can be the most important evidence in evaluating obviousness, *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983), and must always be considered as part of the original determination of obviousness. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986) ("Objective evidence such as commercial success, failure of others, long-felt need, and unexpected results must be considered *before* a conclusion on obviousness is reached and is not merely 'icing on the cake.'") (emphasis in original).

8. The burden of proof by clear and convincing evidence that the claims are obvious in light of *all* the evidence (including secondary considerations) remains with Teva. *Id.* at 1375.

C. Obviousness to One of Skill in the Art

1. Definition of One of Skill in the Art

1. As a prerequisite, the Patent Statute provides that obviousness is to be determined from the perspective of "a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). As the Supreme Court has explained, "[t]o determine whether there was an apparent reason to combine the known elements in

the way a patent claims, it will often be necessary to look to ... the background knowledge possessed by a person having ordinary skill in the art.” *KSR*, 127 S. Ct. at 1740-41.

2. In its notice of Paragraph IV certification notice dated February 20, 2007, Teva defined one of skill in the art as follows:

One of ordinary skill in the art would possess substantial training in chemical and biological sciences with a Ph.D. or equivalent degree, training in the areas of synthetic organic chemistry, pharmacology or a related field, and ***experience working in research and development of leukotriene antagonists*** and leukotrienes biosynthesis inhibitors. This person would have familiarity with the classes of leukotrienes, structure/function relationships of small molecule binding to the leukotrienes receptors as well as standard assays in the art for determining in vivo activity as both leukotriene antagonists or leukotriene biosynthesis inhibitors.

(emphasis added).

3. Teva specifically reaffirmed its standard for one of skill in the art in response to Merck’s interrogatories, and accordingly, Teva is bound to that standard.¹ *See Wechsler v. Hunt Health Sys., Ltd.*, 1999 WL 397751, at *11 (S.D.N.Y. 1999) (a party answering an interrogatory is “afforded ample opportunity fully to reflect upon the question, to consult all pertinent sources of information bearing upon it, and to seek the advice of counsel in order to craft answers that provide a full and accurate disclosure,” and ***interrogatory answers are “judicial admissions’ that estop the answering party***

¹ Teva attempted to revise its definition of one of skill in the art in the Pretrial Order by omitting the requirement for “experience working in research and development of leukotriene antagonists.” Pretrial Order at 54. But Teva remains bound to the standard it set forth in its interrogatory response, not its revised eleventh-hour standard. *Wechsler* at *11.

from later seeking to assert positions omitted from, or otherwise at variance with, those responses.”) (emphasis added).

4. The Federal Circuit recently explained that opinions upon obviousness from those who are not of skill in the art should be ignored:

Nor may a witness not qualified in the pertinent art testify as an expert on obviousness, or any of the underlying technical questions, such as the nature of the claimed invention, the scope and content of the prior art, the differences between the claimed invention and the prior art, or the motivation of one of ordinary skill in the art to combine these references to achieve the claimed invention.

Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1364 (Fed. Cir. 2008), *reh’g denied*, (2009). In summary, testimony about obviousness from experts who are not of skill in the art “serves only to cause mischief and confuse the fact finder.” *Sundance* at 1363.

5. A person of ordinary skill in the art “is presumed to be aware of all the pertinent prior art.” *Custom Accessories, Inc. v. Jeffrey-Allan Indust., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

2. The Lead Compound

1. Throughout this case, including in the Pretrial Order and in its Pretrial Brief, Teva committed to the lead compound obviousness analysis addressed in *Takeda* and *Eisai*. See *Takeda*, 492 F.3d at 1357 (“Alphapharm argues that the prior art would have led one of ordinary skill in the art to select compound b as a lead compound. By ‘lead compound,’ we understand Alphapharm to refer to ***a compound in the prior art that would be most promising to modify*** in order to improve upon its [] activity and

obtain a compound with better activity.”) (emphasis added); *Eisai Co. Ltd. v. Dr. Reddy’s Lab., Ltd.*, 533 F.3d 1353, 1358-1359 (Fed. Cir. 2008) (“This court notes that the district court did not rigidly limit Teva’s obviousness arguments by forcing Teva to select a single lead compound. Rather Teva alone selected lansoprazole as the anchor for its obviousness theory, not the district court.”).

2. The selection of a lead compound must be reasoned and supported by data, including then-available information regarding the entire universe of potential lead compounds in 1990-91. *See Eisai*, at 1358-1359 (rejecting Teva’s obviousness analysis because it failed to begin with the “reasoned” selection of a lead compound); *Takeda* at 1357 (rejecting obviousness analysis based upon a lead compound when “one of ordinary skill in the art would not have selected compound b as the lead compound”).

3. “Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness. By importing the ultimate solution into the problem facing the inventor, the [analysis] adopt[s] an overly narrow view of the scope of the prior art.” *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 (Fed. Cir. 1998) (internal citation omitted).

4. “Patentability is assessed from the perspective of the hypothetical person of ordinary skill in the art, information regarding the subjective motivations of the inventors is not material. ... ‘*Inventors, as a class ... possess something – call it what you will – which sets them apart from workers of ordinary skill... .*’” *Life Techs., Inc. v. Clontech Labs, Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000) (citations omitted) (emphasis added).

3. Differences Between the Prior Art and the Patent Claims

1. Under *Graham*, the “differences between the prior art and the claims at issue should be ascertained” as part of any obviousness challenge. *Graham*, 383 U.S. at 17.

2. Further, in the chemical arts, it is important “to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.” *Takeda*, 492 F.3d at 1357. This inquiry is consistent with the Supreme Court’s decision in *KSR* in which the Court acknowledged the importance in identifying “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the new invention does” as part of the obviousness analysis. *KSR*, 127 S. Ct. at 1741.

3. If a party chose to base its obviousness analysis on the selection of a lead compound structure, it then cannot complain that such an analysis unduly restricts its obviousness analysis. *Eisai*, 533 F.3d at 1358-1359 (“This court notes that the district court did not rigidly limit Teva’s obviousness arguments by forcing Teva to select a single lead compound. Rather Teva alone selected lansoprazole as the anchor for its obviousness theory, not the district court.”)

4. Choosing a lead compound with the benefit of hindsight is improper in an obviousness analysis. *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008) (“In other words, Mylan’s expert [] simply retraced the path of the inventor with hindsight, discounted the number and complexity of alternatives, and concluded that the invention [] was obvious. Of course, this reasoning is always inappropriate for an obviousness test.”); *Astra Aktiebolag v. Andrx Pharma.*, 222 F.

Supp. 2d 423, 581 (S.D.N.Y. 2002), *aff'd sub nom In re Omeprazole Patent Litigation*, 84 Fed. Appx. 26 (Fed. Cir. 2003), *reh'g and reh'g en banc denied*, (2004), *aff'd*, 281 Fed. Appx. 974 (2008), *petition for cert. denied*, 2009 WL 62148 (2009) (The defendant's expert "incorrectly decided obviousness by choosing from a few references one element, and then picking and choosing other elements from other references, all with the knowledge of the solution described in the [patent-in-suit].").

4. There Must be Support for Modifications to the Lead Compound Structure

1. "Where the creation of a chemical compound requires the chemist to pursue several steps in manipulating a compound revealed in the prior art, the patent challenger must show that one of ordinary skill in the art would have had sufficient motivation to take each of those steps." *Takeda*, 492 F.3d at 372. "A prima facie case of obviousness also requires a showing of 'adequate support in the prior art' for the change in structure." *Takeda*, 492 F.3d at 1356 (citation omitted).

2. The Federal Circuit has recognized that an obviousness analysis requiring only two modifications to a lead compound may show that the claimed compound was nonobvious over the prior art. *Takeda*, 492 F.3d at 1357.

3. A lead compound analysis cannot depend upon making modifications that eliminate the very feature for which the lead compound was chosen in the first place. *See Eisai*, 533 F.3d at 1358 ("The record, however, shows no discernible reason for a skilled artisan to begin with lansoprazole only to drop the very feature, the fluorinated substituent, that gave this advantageous property.")

4. “To the extent an art is unpredictable, as the chemical arts often are, *KSR*’s focus on [] ‘identified, predictable solutions’ may present a difficult hurdle because potential solutions are less likely to be genuinely predictable.” *Eisai*, 533 F.3d at 1359.

D. Secondary Considerations

1. Secondary considerations of non-obviousness such as commercial success, long-felt but unresolved need, failure of others, and unexpected results must be considered in determining obviousness. *See Graham*, 383 U.S. at 17-18; *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000).

2. “Indeed, evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not.” *Stratoflex*, 713 F.2d at 1538.

1. Commercial Success

1. The commercial response to an invention is significant to the determinations of obviousness and is entitled to substantial weight. *Graham*, 383 U.S. at 35-36.

2. There must be a sufficient nexus between the commercial success of a product and the patented invention, although it is not necessary that the patented invention be solely responsible for the commercial success of the product. *Continental Can Co., Inc. v. Monsanto Co, Inc.*, 948 F.2d 1264, 1273 (Fed. Cir. 1991); *see generally Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1292-93 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 956 (1988); *Brown Tobacco Corp. v. Phillip Morris, Inc.*,

229 F.3d 1120, 1130 (Fed. Cir. 2000) (“[I]f the marketed product embodies the claimed features and is coextensive with them, then a nexus is presumed and the burden shifts to the party asserting obviousness to present evidence to rebut the presumed nexus.”)

3. Moreover, “a patentee is not required to prove as part of its *prima facie* case that the commercial success is *not* due to factors other than the patented invention. It is sufficient to show that the commercial success was of the patented invention itself.” *Demaco*, 851 F.2d at 1394 (emphasis in original).

4. Substantial sales of a product prove a *prima facie* case of commercial success. *See Takeda Chem. Indus., Ltd., v Mylan Labs Inc.* 417 F.Supp. 2d 341, 386 (S.D.N.Y. 2006) (finding commercial success “can presumptively be attributed to the invention itself” based on annual sales of the patented drug Actos® in excess of \$1.7 billion); *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 438 F. Supp. 2d 479, 494 (D. Del. 2006), *aff’d*, 501 F.3d 1263 (Fed. Cir. 2007) (finding commercial success based on annual sales reaching \$2 billion for patented drug); *See Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 809 n.* (Fed. Cir. 1989).

5. To rebut the *prima facie* showing of a nexus, affirmative evidence is required; mere argument and conjecture are insufficient. *Demaco*, 851 F.2d at 1393 (“It is thus the task of the challenger to adduce evidence to show that the commercial success was due to extraneous factors other than the patented invention, such as advertising, superior workmanship, etc. ... ‘[A]rgument’ and ‘conjecture’ are insufficient.”)(citation omitted).

6. A rebuttal of a *prima facie* showing of obviousness that cannot parse the degree to which sales are attributable to the qualities of the drug should be rejected. *See*

Forest Labs., 438 F.Supp. 2d at 495 (finding expert unpersuasive because “he had no opinion regarding the degree to which sales and prescriptions of Lexapro® are the result of its qualities as an effective drug.”).

2. Long-Felt But Unsolved Need

1. Evidence of long-felt but unsolved need for the invention is an indicator of the nonobviousness of the invention. *See Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1380 (Fed. Cir. 2006) (affirming district court’s conclusion of nonobviousness because it recognized “a ‘long-felt but unsolved need for a safe atypical antipsychotic [drug] from 1975 until 1990’”).

2. Long-felt need is measured from “the date of an articulated identified problem and evidence of efforts to solve that problem,” not from the date of the most pertinent prior art. *Texas Instruments Inc., v. U.S. Int’l Trade Comm’n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993).

3. Unexpected Results

1. Proof that a claimed compound “possess[es] unexpectedly advantageous or superior properties” rebuts a prima facie case of obviousness. *Application of Payne*, 606 F.2d 303, 316 (C.C.P.A. 1979). Indeed, “evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a prima facie case of obviousness.” *Ortho-McNeil*, 348 F. Supp. 2d at 759 (citing *In re Chupp*, 816 F.2d 643, 647 (Fed. Cir. 1987)).

4. Failure of Others

1. Failed attempts by others can “be determinative on the issue of obviousness.” *See Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000); *Electro Scientific Indus., Inc. v. Gen. Scanning Inc.*, 247 F.3d 1341, 1351 (Fed. Cir. 2001) (evidence of failure of others can be demonstrated “through expert testimony, scientific papers and patents.”).

5. Copying

1. Evidence that others have copied the patented invention is also an indicator of nonobviousness. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 679 (Fed. Cir. 1988); *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984); *see Ortho-McNeil*, 348 F. Supp. 2d at 759 (finding that Mylan’s decision to copy Levaquin® instead of other products is significant evidence of nonobviousness).

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**TEVA'S ADDITIONAL STATEMENT OF LAW
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The Law of Obviousness

1. A claim to an invention is invalid under 35 U.S.C. § 103, where the subject matter of the claimed invention so resembles the prior art that it would have been obvious to one of ordinary skill in the relevant art. 35 U.S.C. § 103(a).

2. Although generally obviousness must be proven by clear and convincing evidence, where a material prior art reference upon which the obviousness defense relies was not before the examiner during prosecution of the patent, the evidentiary standard for proving invalidity should be only by a preponderance of the evidence. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007) (noting that the rationale underlying the presumption of an issued patent's validity is "much diminished" when prior art upon which defense relies was not before the PTO).

3. In *KSR*, the Supreme Court recently clarified the standard for obviousness under § 103, noting that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR*, 550 U.S. at 420. In certain instances the reason to combine may "come from the nature of a problem to be solved, leading inventors to look to references relating to possible solutions to that problem." *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

4. Further, the Supreme Court cautioned that "[t]he obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents." *KSR*, 550 U.S. at 419. Instead, the Supreme Court advised that a more flexible approach is appropriate; obviousness may be established by "noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." *KSR*, 550 U.S. at 420.

Person Of Ordinary Skill In The Art

1. Obviousness is determined from the point of view of a person of ordinary skill in the art (“POSA”). A POSA is not an actual person, but rather is a *hypothetical* person whom the law presumes has knowledge of all prior art references in the field of the invention. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *Endress-Hauser, Inc. v. Hawk Measurement Systems Pty. Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997) (“Defendants attack [plaintiff’s expert] on the grounds that he is not ‘a person of ordinary skill in the art,’ and that he at one point in the proceedings acknowledged that much. Of course that objection is meritless. The ‘person of ordinary skill in the art’ is a theoretical construct used in determining obviousness under § 103, and is not descriptive of some particular individual.”).

2. Courts in chemical cases routinely define a POSA as a “medicinal chemist” with general experience with drug development. *See, e.g., Altana Pharma AG v. Teva Pharmaceuticals USA, Inc.*, 532 F.Supp.2d 666, 676 & n.17 (D.N.J. 2007) (noting that for a patent claiming proton pump inhibitor compounds “[t]he parties agree that a person of ordinary skill in the art is a medicinal chemist,” and that “more specification is unnecessary, as the requirement, in practice, reminds judges to put themselves in the shoes of one skilled in the art, as opposed to compelling a particular factual finding”); *see also Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1356 (Fed. Cir. 2007) (affirming district court’s definition of a person of ordinary skill in the art of acid addition salts of dihydropyridine compounds as someone with “a bachelor’s degree in pharmaceutical science or analytical chemistry, and some experience in drugs and drug preparation.”)

Prima Facie Obviousness: Structural Similarity

1. The *prima facie* obviousness of a chemical compound may be “based upon structural similarity, *i.e.*, an established structural relationship between a prior art compound and the claimed compound.” *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995).

2. “Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds.” *Id.*; *see also In re Mayne*, 104 F.3d 1339, 1342 (Fed. Cir. 1997) (citing *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc)). “For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.” *Deuel*, 51 F.3d at 1558.

3. In analyzing the obviousness of a chemical compound, it is not necessary to identify or select a single, best lead compound in the prior art. *See, e.g., Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1358-59 (Fed. Cir. 2008) (noting with approval that “the district court did not rigidly limit Teva’s obviousness arguments by forcing Teva to select a single lead compound” and explaining that “KSR assumes a starting reference point or points in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions”).

4. To establish a *prima facie* case of obviousness, it is not necessary to show that success was absolutely predictable. *See Pfizer*, 480 F.3d at 1364 (“Indeed, a rule of law equating unpredictability to patentability . . . cannot be the proper standard since the expectation of success need only be reasonable, not absolute.”); *see also KSR*, 550 U.S. at 421; *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986); *Imperial Chemical Industries, PLC v. Danbury Pharmacal, Inc.*, 777 F. Supp. 330, 344-46 (D. Del. 1991), *aff’d*, 972 F.2d 1354 (Fed.

Cir. 1992) (finding prior art drug-receptor model demonstrating certain “common and necessary” features of an active drug compound rendered a compound possessing those features *prima facie* obvious because the model provided a “high expectation” that any compound with those features would be an active drug).

5. If routine testing is needed to verify expected results and the means of making a compound are available to a skilled artisan, claims may be obvious even if the results were not entirely predictable. *Pfizer*, 480 F.3d at 1365-66. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR*, 550 U.S. at 416.

6. That there exist other obvious embodiments based on a combination of prior art references does not negate the obviousness of any particular embodiment. *See Merck & Co. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 806-07 (Fed. Cir. 1989) (noting that fact that a prior art patent disclosed 1,200 possible effective combinations “does not render any particular formulation less obvious”).

Secondary Considerations

1. Secondary considerations, or “objective” indicia of non-obviousness, “such as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *Graham*, 383 U.S. at 17-18; *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07 (2007).

2. “Although secondary consideration must be taken into account, they do not necessarily control the obviousness conclusion,” and may not be sufficient to overcome a strong showing of obviousness. *Pfizer v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007); *see also Rothman v. Target Corp.*, No. 2008-1375, (Fed. Cir. Feb. 13, 2009), slip op. at 16 (“Indeed, a strong prima facie obviousness showing may stand even in the face of considerable evidence of secondary considerations.”).

3. Additionally, in an obviousness decision, “[a] nexus between the merits of the claimed invention and evidence of secondary considerations is required in order for the evidence to be given substantial weight.” *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 668 (Fed. Cir. 2000) (citation omitted).

4. Where the patentee has a substantial patent portfolio that precludes competitors from competing with the alleged invention of the patent-in-suit, evidence of financial success of the patented invention is far less probative of non-obviousness. *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005) (“Although commercial success might generally support a conclusion that Merck’s claimed invention was non-obvious in relation to what came before in the marketplace, the question at bar is narrower. It is whether the claimed invention is non-obvious in relation to the ideas set forth in the [closest prior art]. Financial success is not

significantly probative of that question in this case because others were legally barred from commercially testing the [prior art] ideas.”).

5. Similarly, where the patentee has engaged in extensive advertisement and promotion of its commercial product, any inference of non-obviousness based on commercial success is weakened. *McNeil-PPC, Inc. v. Perrigo Co.*, 516 F.Supp.2d 238, 254-55 (S.D.N.Y. 2007) (finding that an advertising campaign of over \$90 million per year weakened the commercial success inference).

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s/ Michael E. Patunas

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